K031087

APR 2 4 2003

510(k) Summary

A. Submitter Information

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Edwards Lifesciences
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B. Device Information

1. Trade Name:

   Edwards Introducer Sheath

2. Common or Usual Name:

   Catheter Introducer

3. Device Classification and Classification Name:

   Class II (DYB, 21 CFR 870.1340 Catheter introducer)

4. Predicate Device Identification:
   Cook® Extra Large Check-Flo® Introducer (K902469)
   Guidant Ancure® Sheath (K003889)

5. Device Description:

   The subject device is comprised of an introducer and introducer sheath. The introducer has a tapered soft/flexible tip and is inserted into the introducer sheath, then inserted into the vessel over a guidewire as an assembly. At the proximal end of the sheath the body tubing is connected to a head assembly. The head assembly consists of a housing that contains three hemostasis valves

to minimize blood loss. A side port extension with a three-way stopcock allows for the introduction of anticoagulant, as needed. Once the Introducer/Sheath Assembly has been placed within the vessel, the introducer is removed and the sheath is left in place. The sheath provides and maintains a pathway for the introduction of interventional devices.

6. Intended Use:

   The subject device is designed to facilitate the entry of interventional devices into the human vascular system.

7. Technological Comparison of Subject Device to Predicate Device:

   The physical characteristics, the intended use and the mode of use of the subject device are similar to the predicate devices.

8. Summary of Non-Clinical Tests and Conclusions:

   In vitro performance testing and biocompatibility evaluations were conducted on the subject device as part of an endovascular graft delivery system. Tests specific to the subject device include bond tensile strength, free passage of a guidewire, kink resistance of both the introducer and the sheath, and the flow rate. All testing demonstrated that the subject device met its acceptance criteria.

9. Summary of Clinical Tests and Conclusions:

   The subject device is used as part of a system for the deployment of endovascular grafts. The systems are CE marked and commercially available in the European Union. To date, subject devices have been used successfully with few complaints reported.

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C. Submitter's Signature and Date of Summary Preparation

Daun L. Putnam 4/3/03

Daun Putnam
Regulatory Specialist

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

Edward Lifesciences, LLC
Mr. Daun Putman
Regulatory Specialist
One Edward Way
Irvine, CA 92614-5686

Re: K031087
Trade/Device Name: Edward Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DYB
Dated: April 4, 2003
Received: April 10, 2003

Dear Mr. Putman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031087

Indications for Use

Reference: 510(k) Notification for the Edwards Introducer Sheath

The Edwards Introducer Sheath is designed to facilitate the entry of interventional devices into the human vascular system.

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031087